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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/157,984	09/22/1998	KWOK ON LAI	007198-353	3201
23562	7590	12/15/2003	EXAMINER	
BAKER & MCKENZIE PATENT DEPARTMENT 2001 ROSS AVENUE SUITE 2300 DALLAS, TX 75201			HAYES, ROBERT CLINTON	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

9.14

## Office Action Summary

08-14

### Application No.

09/157,984

### Applicant(s)

LAI ET AL.

### Examiner

Robert C. Hayes, Ph.D.

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-5 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. The amendments filed 4/06/01, 7/13/01, 10/24/01, 2/06/02 and 9/10/03 have been entered.
2. Newly submitted/amended claim 4 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 4 is directed toward methods, versus the elected products, that are classified in Class 514/subclass 12, versus Class 530/subclass 399 of the instant elected invention. The new method of claim 4 is distinct from the products of elected Group I because the method of claim 4 requires patients with "acute and/or chronic neuronal injury or neurodegenerative disease states", which are not required in the products of elected Group I. Therefore, because each group has acquired a separate status in the art as shown by their different classification, and because the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 4 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claim 4 drawn to an invention nonelected **without** traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The Katz Declarations by Lai and by Ip under 37 CFR 1.132 filed 4/06/01 are sufficient to overcome the rejection of claims 1 & 3 under 35 U.S.C. 102(a) as being anticipated by Lai et al.

4. Applicant's arguments filed 4/06/01 have been fully considered but they are not deemed to be persuasive.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The abstract of the disclosure is objected to because the Abstract must be a single paragraph. Correction is required. See MPEP § 608.01(b).

7. Claim 3 is objected to because compositions require at least 2 components. It is suggested that amending claim 3 to include a "carrier" should obviate this objection.

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8. Claims 1 & 3 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper #10, and as follows.

As previously made of record, the specification solely describes carp NT-7 as depicted in SEQ. ID NO 1. No written description of any different NT-7 polypeptides that can be structurally envisioned by one skilled in the art (i.e., by amino acid sequence) are disclosed within the specification, including what structurally constitutes a single "functional variant, analogue and functional fragments" thereof; thereby, still not meeting the written description requirements of 35 U.S.C. § 112, first paragraph.

Accordingly, *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) held that "an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Moreover,

"[o]ne skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is". *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997).

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

Applicant is directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999. For example, see Example 13.

9. Claims 1 & 3 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the carp NT-7 polypeptide of SEQ ID NO: 1, or functional variants thereof that increase survival and neurite outgrowth of embryonic chick DRG neurons, does not reasonably provide enablement for NT-7 polypeptides with no recited functionally characteristics, nor any biologically functional equivalents of such without specific structural and functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons made of record in Paper #10, and as follows.

As previously made of record, the specification does not teach which particular amino acids are critical for any NT-7 protein's function, nor how to distinguish such from any different polypeptide sequences that possess none of the desired functions of the instant invention. Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for any NT-7 protein's function would prevent the skilled artisan from determining whether any random "functional variants, analogues and functional fragments" to the specific amino acid sequence of SEQ ID NO: 1 could be made which retains the desired function of the instant invention, because any random mutation, modification or truncation

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manifested within such polypeptides would be predicted to adversely alter its biologically active 3-dimensional conformation, without requiring undue experimentation to determine otherwise; consistent with the teachings of Rudinger previously made of record.

10. Claims 1 & 3 stand rejected under 35 U.S.C. 102(a) as being anticipated by Nilsson et al., for the reasons made of record in Paper No: 10.

The Declaration by Ip filed on 4/06/01 under 37 CFR 1.131 has been considered but is ineffective to overcome the Nilsson et al reference, because it is not signed by all inventors. See MPEP 715.04.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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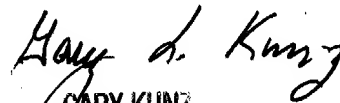
Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
December 5, 2003



GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600